PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61N 5/10 | A1

(11) International Publication Number: WO 97/40889

(43) International Publication Date: 6 November 1997 (06.11.97)

(21) International Application Number: PCT/US97/07183

(22) International Filing Date: 29 April 1997 (29.04.97)

(30) Priority Data:

60/016,498	30 April 1996 (30.04.96)	US
08/748,698	13 November 1996 (13.11.96)	US
60/035,761	6 January 1997 (06.01.97)	US

(71)(72) Applicants and Inventors: APPLE, Marc, G. [US/US]; 29801 Warwick Court, Novi, MI 48377 (US). APPLE, Melvin, J. [US/US]; 2553 N.W. 52nd Street, Boca Raton, FL 33496 (US).

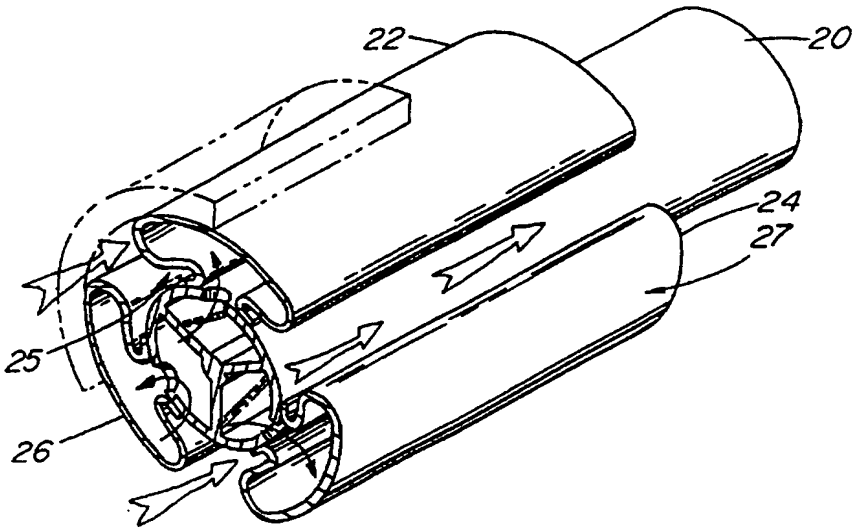
(74) Agent: GODLEWSKI, Richard, J.; P.O. Box 2256, West Lafayette, IN 47906 (US).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.
With amended claims.

Date of publication of the amended claims:
18 December 1997 (18.12.97)

(54) Title: CATHETER SYSTEM WITH BALLOON CONTAINING A RADIOACTIVE FLUID



(57) Abstract

A catheter apparatus filled with a radiation carrier material such as an inert radioactive gas for the treatment of restenosis after angioplasty, and malignancies. The inflated catheter includes a plurality of discrete chambers for transporting the radioactive carrier material, and a plurality of discrete chambers enabling substantial blood flow through the artery during treatment with the prescribed radiation. The inflated catheter may also comprise one unit balloon. A specific metal coating enhances the radiation dose delivered to the target. The wall of the lumen attenuates transmission dose to the blood circulating through the hollow inner lumen of the catheter device. The system also creates increased by-product radiation, from the impact of beta particles and gamma protons traveling toward the lumen wall. In addition, two opposing balloons whereby gas-tight redirection of radioactive gas flow from one balloon to the other, enabling one balloon to be inflated and delivered treatment dose, while the opposing balloon is deflated.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

AMENDED CLAIMS

[received by the International Bureau on 28 October 1997 (28.10.97);
original claim 1 amended; new claims 20-57 added; remaining claims unchanged (9 pages)]

1. Catheter apparatus for irradiating internal tissue of a patient, wherein the catheter apparatus comprises means for connection to a supply of radioactive fluid; wherein the catheter is capable of being inserted either into, or adjacent to, the said tissue; and wherein the catheter apparatus comprises a tissue compliant balloon section, at least part thereof being inflatable by the radioactive fluid in order to correctly locate the radioactive fluid relative to the said tissue and to deliver a homogeneous radiation dose and/or homogeneous radiation dose rate.

2. Catheter apparatus according to claim 1, wherein the balloon section comprises either a single balloon or a plurality of balloons, each being inflatable at the outer periphery of the catheter, each balloon being connectable to and inflatable by the radioactive fluid.

3. Catheter apparatus according to claim 2, wherein each of the said plurality of balloons is arranged either around a respective peripheral part of the catheter, or along a respective longitudinal part of the catheter.

4. Catheter apparatus according to claim 2 or 3, wherein the catheter is designed for location within a body passageway, and wherein each balloon is inflatable so as to contact the wall of the passageway.

5. Catheter apparatus according to claim 4, wherein each balloon has an inner surface and an outer surface, and wherein the outer surface of each balloon enables optimal penetration of the said tissue by radiation.

6. Catheter apparatus according to claim 5, wherein the inner surface of each balloon increases the attenuation of the radiation penetrating by body fluid (for example blood) in the said passageway.

7. Catheter apparatus according to any one preceding claim, wherein the catheter balloon section is designed for post-angioplasty or other recannulation procedures for minimizing restenosis, or for treating malignant diseases or benign hyperproliferative type diseases.

8. Catheter apparatus according to any one of claims 1 to 6, wherein the catheter is designed for the treatment or prevention of restenosis.

9. Catheter apparatus according to any one preceding claim, wherein the radioactive fluid is a krypton, neon, radon, or xenon gas or an isotope thereof.

10. Catheter apparatus according to any one of claims 1 to 8, wherein the radioactive fluid is liquid or a gel compound of phosphorous, rhenium, osmium, vanidum, ruthenium, bismuth, yttrium, technetium, iodine, gallium, chromium, strontium, thallium, samarium, ytterbium, palladium, or an isotope, compounding or binding solution thereof.

11. Catheter apparatus according to any one preceding claim, wherein the radioactive fluid is designed to emit beta and/or gamma particles.

12. Catheter apparatus according to any one of claims 6 to 9, wherein the inner surface of each balloon is either of thicker cross-section or of increased attenuation material or both.

13. Catheter apparatus according to any one preceding claim, wherein the catheter further comprises a movable shield designed to protect body parts adjacent to the said tissue.

14. Catheter apparatus according to any one preceding claim, wherein the catheter has a catheter wall which includes a metallic based material.

15. Catheter apparatus according to claim 14, wherein the metal material is a specific layer of a heavy transitional metal, or is metal selected from titanium, germanium, tungsten, aluminum, a titanium alloy, a germanium alloy, a tungsten alloy, and an aluminum alloy.

16. Catheter apparatus according to claim 14 or 15, wherein the balloon section comprises one part to be inflated whilst another part is to be simultaneously deflated.

17. A catheter apparatus according to any one preceding claim, wherein the fluid, preferably, injected radio- or non-radio gas(es) and/or liquid(s), are induced in the balloon to undergo electron stimulation, whereby by-product fluorescent, phosphorescent, and/or luminescent radiant energy for therapeutic purposes can be produced.

18. A catheter apparatus according to any one preceding claim, wherein the catheter system has an injection and/or directional entry port which minimizes risk of gas leakage and allows for directional control of fluid.

19. A catheter apparatus according to any one preceding claim, wherein the catheter system includes means for electrical conductance or potential to be applied to an inflated balloon.

20. Catheter apparatus for at least partial insertion within a passageway of internal tissue of a patient, said passageway being for the purpose of permitting a bodily fluid to flow therethrough, said apparatus comprising a balloon section, at least part thereof being inflatable by radioactive fluid in order to correctly direct radiation towards at least one part of the said passageway, and means (12) for supplying the radioactive fluid to the balloon section, wherein the

balloon section is formed in such a way that when inflated, to at least one inflated condition, the body fluid is able to flow past the inflated balloon section.

21. Catheter apparatus according to claim 20, wherein the balloon section comprises either a single balloon or a plurality of balloons, each being inflatable at the outer periphery of the catheter, each balloon being connectable to and inflatable by the radioactive fluid.

22. Catheter apparatus according to claim 21, wherein each of the said plurality of balloons is arranged either around a respective peripheral part of the catheter, or along a respective longitudinal part of the catheter.

23. Catheter apparatus according to claim 21 or 22, wherein each balloon is inflatable so as to contact the wall of the passageway.

24. Catheter apparatus according to claim 23, wherein each balloon has an inner surface and an outer surface, and wherein the outer surface of each balloon enables optimal penetration of the said tissue by radiation.

25. Catheter apparatus according to claim 24, wherein the inner surface of each balloon increases the attenuation of the radiation penetrating by body fluid (for example blood) in the said passageway.

26. Catheter apparatus according to any one of claims 20 to 25, wherein the catheter balloon section is designed for post-angioplasty or other recannulation procedures for minimizing restenosis, or for treating malignant diseases or benign hyperproliferative type diseases.

27. Catheter apparatus according to any one of claims 20 to 25, wherein the catheter is designed for the treatment or prevention of restenosis.

28. Catheter apparatus according to any one of claims 20 to 27, wherein the radioactive fluid is a krypton, neon, radon, or xenon gas or an isotope thereof.

29. Catheter apparatus according to any one of claims 20 to 27, wherein the radioactive fluid is liquid or a gel compound of phosphorous, rhenium, osmium, vanidum, ruthenium, bismuth, yttrium, technetium, iodine, gallium, chromium, strontium, thallium, samarium, ytterbium, palladium, or an isotope, compounding or binding solution thereof.

30. Catheter apparatus according to any one of claims 20 to 29, wherein the radioactive fluid is designed to emit beta and/or gamma particles.

31. Catheter apparatus according to any one of claims 25 to 28, wherein the inner surface of each balloon is either of thicker cross-section or of increased attenuation material or both.

32. Catheter apparatus according to any one of claims 20 to 31, wherein the catheter further comprises a movable shield designed to protect body parts adjacent to the said tissue.

33. Catheter apparatus according to any one of claims 20 to 32, wherein the catheter has a catheter wall which includes a metallic based material.

34. Catheter apparatus according to claim 33, wherein the metal material is a specific layer of a heavy transitional metal, or is metal selected from titanium, germanium, tungsten, aluminum, a titanium alloy, a germanium alloy, a tungsten alloy, and an aluminum alloy.

35. Catheter apparatus according to claim 33 or 34, wherein the balloon section comprises one part to be inflated whilst another part is to be simultaneously deflated.

36. A catheter apparatus according to any one of claims 20 to 35, wherein the fluid, preferably, injected radio- or non-radio gas(es) and/or liquid(s), are induced in the balloon to undergo electron stimulation, whereby by-product fluorescent, phosphorescent, and/or luminescent radiant energy for therapeutic purposes can be produced.

37. A catheter apparatus according to any one of claims 20 to 36, wherein the catheter system has an injection and/or directional entry port which minimizes risk of gas leakage and allows for directional control of fluid.

38. A catheter apparatus according to any one of claims 20 to 37, wherein the catheter system includes means for electrical conductance or potential to be applied to an inflated balloon.

39. A catheter apparatus according to any one of claims 20 to 38, wherein said catheter apparatus further comprises radiation protection means (25) for protecting from irradiation body fluid flowing adjacent to that part of the balloon section remote from the said passageway.

40. Catheter apparatus for at least partial insertion within a passageway of internal tissue of a patient, said passageway being for the purpose of permitting a body fluid to flow therethrough, said apparatus comprising a balloon section, means for supplying radioactive fluid to the balloon section in order to inflate the latter or at least part thereof, and to thereby correctly direct radiation to at least one part of the passageway, and radiation protection means (25) for protecting from irradiation body fluid flowing adjacent to that part of the balloon section remote from the said passageway.

41. Catheter apparatus according to claim 40, wherein the balloon section comprises either a single balloon or a plurality of balloons, each being inflatable at the outer periphery of the catheter, each balloon being connectable to and inflatable by the radioactive fluid.

42. Catheter apparatus according to claim 41, wherein each of the said plurality of balloons is arranged either around a respective peripheral part of the catheter, or along a respective longitudinal part of the catheter.

43. Catheter apparatus according to claim 41 or 42, wherein each balloon is inflatable so as to contact the wall of the passageway.

44. Catheter apparatus according to claim 43, wherein each balloon has an inner surface and an outer surface, and wherein the outer surface of each balloon enables optimal penetration of the said tissue by radiation.

45. Catheter apparatus according to claim 44, wherein the inner surface of each balloon increases the attenuation of the radiation penetrating by body fluid (for example blood) in the said passageway.

46. Catheter apparatus according to any one of claims 40 to 45, wherein the catheter balloon section is designed for post-angioplasty or other recannulation procedures for minimizing restenosis, or for treating malignant diseases or benign hyperproliferative type diseases.

47. Catheter apparatus according to any one of claims 40 to 45, wherein the catheter is designed for the treatment or prevention of restenosis.

48. Catheter apparatus according to any one of claims 40 to 47, wherein the radioactive fluid is a krypton, neon, radon, or xenon gas or an isotope thereof.

49. Catheter apparatus according to any one of claims 40 to 47, wherein the radioactive fluid is liquid or a gel compound of phosphorous, rhenium, osmium, vanidum, ruthenium, bismuth, yttrium, technetium, iodine, gallium, chromium, strontium, thallium, samarium, ytterbium, palladium, or an isotope, compounding or binding solution thereof.

50. Catheter apparatus according to any one of claims 40 to 49, wherein the radioactive fluid is designed to emit beta and/or gamma particles.

51. Catheter apparatus according to any one of claims 45 to 48, wherein the inner surface of each balloon is either of thicker cross-section or of increased attenuation material or both.

52. Catheter apparatus according to any one of claims 40 to 51, wherein the catheter further comprises a movable shield designed to protect body parts adjacent to the said tissue.

53. Catheter apparatus according to any one of claims 40 to 52, wherein the catheter has a catheter wall which includes a metallic based material.

54. Catheter apparatus according to claim 53, wherein the metal material is a specific layer of a heavy transitional metal, or is metal selected from titanium, germanium, tungsten, aluminum, a titanium alloy, a germanium alloy, a tungsten alloy, and an aluminum alloy.

55. Catheter apparatus according to claim 53 or 54, wherein the balloon section comprises one part to be inflated whilst another part is to be simultaneously deflated.

56. A catheter apparatus according to any one of claims 40 to 55, wherein the fluid, preferably, injected radio- or non-radio gas(es) and/or liquid(s), are induced in the balloon to undergo electron stimulation, whereby by-product fluorescent, phosphorescent, and/or luminescent radiant energy for therapeutic purposes can be produced.

57. A catheter apparatus according to any one of claims 40 to 56, wherein the catheter system has an injection and/or directional entry port which minimizes risk of gas leakage and allows for directional control of fluid.

58. A catheter apparatus according to any one of claims 40 to 57, wherein the catheter system includes means for electrical conductance or potential to be applied to an inflated balloon.

59. A catheter apparatus according to any one of claims 40 to 58, wherein the balloon section is formed in such a way that when inflated, to at least one inflated condition, the body fluid is able to flow past the inflated balloon section.